

REMARKS

In view of the above amendments and the following remarks, reconsideration and further examination are respectfully requested.

In the previous response, claims 1-13 and 21-85 were canceled without prejudice. In the present response, no claims have been amended. Claims 103-127 have been added. It is believed that the new claims correspond to the elected Group II invention. In addition, the new claims are supported by the application as originally filed. For example, support for claims 103-111 can be found on pages 6-8, 11 and 12 of the specification and in FIGS. 1, 2 and 5 of the drawings as well as elsewhere throughout the application. As another example, support for claims 113-116 can be found on pages 6-8 10 and 11 of the application and FIGS. 1, 2, 5 and 6 of the drawings as well as elsewhere throughout the originally filed application. In still yet another example, support for claims 122-127 can be found on pages 6 and 12 of the specification and in FIG. 5 of the drawings as well as elsewhere throughout the application. It should be noted that on page 10 of the present application, U.S. Patent No. 5,879,311, which was incorporated by reference, provides supplemental support for these claims as well. As a result of these amendments, claims 14-20 and 86-127 are currently pending and under consideration.

Objection to Specification

In item 2 of the Office Action, the specification was objected to for minor informalities. The cited informalities have been corrected.

Claim Rejections Under 35 USC §112

Claims 14-20, 97, and 99-102

In item 4 of the Office Action, claims 14-20, 97, and 99-102 were “rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.” In particular, it was alleged that the “original disclosure fails to provide sufficient support for the claimed method being carried out on a ‘non-digit body part’, ‘an earlobe’, ‘a limb’, or a ‘region of skin where nerve density is low and supply of body fluid is low’ as set forth in claims 14, 20, 97, 99 and 102.”

It is well-settled law that the Patent Office has the initial burden of showing that a claim fails to satisfy the written description requirement. *See*, Manual of Patent Examining Procedures

8th Edition (MPEP) §2163.04. In traversal, the Applicants submit that the Patent Office has failed to meet this burden by failing to show that claims 14-20, 97, and 99-102 do not satisfy the written description requirement.

One purpose of the written description requirement is to assure that the inventors were in possession of the invention being claimed at the time the application was filed. “To fulfill the written description requirement, the patent specification must describe an invention in sufficient detail that one skilled in the art can clearly conclude that the inventor invented what is claimed.” *Cordis Corp. v. Medtronic AVE Inc.*, 67 USPQ2d 1876, 1885 (Fed. Cir. 2003). However, the disclosure as originally filed does not have to provide in *haec verba* or exact language support for the claimed subject matter at issue. *See, Id.* and *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570, 39 USPQ2d 1895 (Fed. Cir. 1996). Rather, as noted in §2163 of the MPEP, “[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.” (emphasis added).

From reviewing the present application, one skilled in the art would have reasonably concluded that the inventors of the present application had possession of the claimed inventions of claims 14-20, 97, and 99-102. The present application describes a lancing device (10) with an integrated disposable (12) that is configured to be able to collect and analyze body fluid from alternate sites, such as earlobes and limbs. As discussed in the present application, although alternate site locations typically are less sensitive to pain, they also tend to bleed less. If needed, the stimulator member (24) on the lancing device (10) is used to express fluid.

The originally filed application clearly provides support for the above-mentioned claims. For example, the originally filed application on page 1, lines 16-22 states (emphasis added):

Blood is most commonly taken from the fingertips, where the supply is generally excellent. However, the nerve density in this region causes significant pain in many patients. Sampling of **alternate sites, such as earlobes and limbs**, is sometimes practiced to access sites which are **less sensitive**. These sites are also **less likely to provide excellent blood samples** and make blood transfer directly to test devices difficult.

Repeated lancing in limited surface areas (such as fingertips) results in callous formation. This leads to increased difficulty in drawing blood and increased pain.

Indeed, page 6, lines 8-9 of the original application states that an “object of this invention is to provide a method by which the drawn sample is collected and may be easily presented to a testing device, regardless of the location of the sample site on the body.” When describing one embodiment in the “DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION” section, the originally filed application states on page 10, lines 16-23:

Following the cutting of an incision I in the skin and the retraction of the lancet, the housing can be repeatedly pushed downwardly against the skin as required to express the appropriate sample from the incision, whereupon the sleeve depresses a ring of body tissue in surrounding relationship to the incision, causing the incision to bulge while spreading apart the sides of the incision. Consequently, a drop D of body fluid such as blood or interstitial fluid is formed at the open end of the incision, even if the incision I has been made in a region of the body where the supply of body fluid is relatively low as compared to, say, the fingertip region.

Again, the written description requirement does not require exact language support for the claimed subject matter. One of ordinary skill in the art would have clearly recognized that a “non-digit part” refers to body parts other than the fingers (or toes), which is merely reciting an alternate site in another way, and thus, such a feature was supported by the originally filed application. As noted before, the present application expressly supports the recitation of “an earlobe” and “a limb”, and one of ordinary skill in the art would have easily recognized that the inventors of the present application had in their possession “a region of skin where nerve density is low and supply of body fluid is low.” For these and other reasons, it is submitted that claims 14-20, 97, and 99-102 are supported by the originally filed application. Therefore, it is requested that the rejections of item 4 be withdrawn.

Claims 86-98

Item 6 of the Office Action, claims 86-98 were rejected under 35 U.S.C. §112, second paragraph as being indefinite. Specifically, it was asserted that “the meaning of ‘alternate site’ by itself is unclear because a non-alternate site has not been previously recited in the claim.” The Applicants respectfully traverse, because it is submitted that one of ordinary skill in the art, after reading the claims and specification, would understand the metes and bounds of independent claim 86 and its dependent claims.

In rejecting a claim under the Second Paragraph of 35 U.S.C. 112, it is incumbent on the Patent Office to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the supporting specification, would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims. Ex parte Wu, 10 USPQ 2d 2031, 2033 (B.P.A.I. 1989 citing (In Re Moore), 439 F.2d 1232, 169 USPQ 236 (C.C.P.A. 1971); In Re Hammack, 427 F.2d 1378, 166 USPQ 204 (C.C.P.A. 1970)) (emphasis added). As stated in §2173.02 of the MPEP, “[t]he examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available.” Furthermore, “definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.” MPEP §2173.03. It appears that the Office Action is unnecessarily requiring the incorporation of additional features into the claims to suit the Patent Office’s taste without explaining how or why one of ordinary skill would not reasonably recognize the metes and bounds of the claims.

Even without reading the present application, one of ordinary skill in the art would have reasonably recognized metes and bounds of independent claim 86 because “alternate site” is a commonly used term in the art to refer to a region of the body other than the fingers, such as a limb or earlobe. This understanding would have been reinforced after reading the present application. For example, the originally filed application on page 1, lines 16-22 describes:

Blood is most commonly taken from the fingertips, where the supply is generally excellent. However, the nerve density in this region causes significant pain in many patients. Sampling of alternate sites, such as earlobes and limbs, is sometimes practiced to access sites which are less sensitive. These sites are also less likely to provide excellent blood samples and make blood transfer directly to test devices difficult. (emphasis added)

Considering that one of ordinary skill in the art would have clearly recognized what constitutes an alternate site, independent claim 86 is definite, and the need to recite what is not an alternate site is unnecessary. For the reasons discussed above, it is respectfully submitted that claims 86-98 are not indefinite and withdrawal of the rejection is respectfully requested.

Claim Rejections Under 35 USC §102

Independent Claim 86

In item 8 of the Office Action, independent claims 86 was “rejected under 35 U.S.C. 102(b) as being anticipated by Garcia et al. (US 4,637,403).” In the Office Action, it was purported that “an alternate site as stated in the claim can be considered a finger tip.” However, such an interpretation stretches the meaning of “alternate site” beyond what one of ordinary skill in the art would consider reasonable. “Although the PTO must give claims their broadest reasonable interpretation, this interpretation must be consistent with the one that those skilled in the art would reach.” In re Cortright, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1467 (Fed. Cir. 1999); see, Manual of Patent Examining Procedure (MPEP) §2111. The Office Action failed to provide the broadest reasonable interpretation for this feature. One of ordinary skill in the art would consider the interpretation provided in the Office Action to be unreasonable because such an interpretation is exactly the opposite of the meaning of “alternate site.” As discussed above, one of ordinary skill in the art would have not considered a fingertip as corresponding to an alternate site. Rather, one of ordinary skill in the art would have considered locations other than fingertips, such as limbs and earlobes, as being alternate sites. Looking at the drawings, Garcia merely discloses lancing fingers and not alternate sites. Considering that Garcia fails to disclose all of the features recited in claim 86, it is submitted that claim 86 and its dependent claims are not anticipated by Garcia. Withdrawal of the rejection of item 8 is respectfully requested.

Claim Rejections Under 35 USC §103

Independent Claim 14

In item 16 of the Office Action, independent claim 14 was “rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. (US 4,637,403) in view of Cusack et al. (US 5,314,441).” In the Office Action, it was recognized that “Garcia does not expressly disclose placing the sampling device on a non-digit body part, an earlobe, a limb, or a region of skin where nerve density is low and the supply of body fluid is low.” However, it was purported that “Cusack teaches taking blood samples on alternative sites such as a foot, arm or leg for the purpose of obtaining blood sample from neonates or persons with poor circulation (column 1, lines 17-21). Therefore, it would have been obvious to one having ordinary skill in the art at the

time of invention to have placed a sampling device on an arm or leg as taught by Cusack in the method of Garcia in order to obtain a blood sample from neonates or persons with poor circulation.” In traversal, the Applicants submit that a *prima facie* case of obviousness has not been established because there has been shown no proper teaching, suggestion or motivation to modify the cited reference in the manner that has been asserted in the Office Action to be obvious. When properly considered, the only suggestion of the presently claimed invention is provided by the present application.

A *prima facie* case of obviousness cannot be based upon a modification of a reference that destroys the intent, purpose or function of the invention disclosed in the cited reference, because there would be no technological motivation for making the modification or change, but rather, there would be a disincentive for making such as change. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Cusack teaches away from using a plunger cut to form incisions of the type described in Garcia, and instead, Cusack teaches utilizing a slice cut to form an incision. For example, Cusack at column 2, lines 7-9 teaches that plunger cuts require “a relatively deep incision must be made to ensure enough capillaries are severed to achieve the necessary bleeding.” As discussed at column 2, lines 10-15 of Cusack:

Another disadvantage associated with plunge cut lancet devices is that they are painful. As will be recognized by any person skilled in the art, a plunge incision is more traumatic than an incision made by a scalpel slice. As such, there is less pain associated with a slice incision than with a plunge incision. Slice incisions as indicated are less intrusive and heal more readily.

Looking at the drawings, the systems described in Garcia utilize a plunge cut in order to cut incisions into the skin, which is contrary to the teachings of Cusack. After reading Cusack, one of ordinary skill in the art would have been motivated away from using the plunge cut systems described in Garcia to form incisions, especially at alternate sites which would require painfully deep incisions to ensure that a sufficient number of capillaries are cut to achieve proper bleeding. Considering that the teachings of Cusack are the opposite to the teachings of Garcia, there is no motivation to combine the teachings of the two references, and in fact, there is a disincentive to combine the references.

Without the benefit of hindsight gained from viewing the present application, one of ordinary skill in the art at the time of the invention would not have modified the cited references as asserted in the Office Action to arrive at the invention as recited in the present claim 14. For

these and other reasons, the Applicants respectfully submit that independent claim 14 along with its dependent claims are allowable over the references of record and request that the rejection of these claims under 35 U.S.C. § 103 be withdrawn.

Independent Claim 99

In item 16 of the Office Action, independent claim 99 was “rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. (US 4,637,403) in view of Cusack et al. (US 5,314,441).” In traversal, it is submitted that even when combined together, both of the references fail to disclose all of the features recited in claim 99, such as “expressing the body fluid from the incision with the stimulator sleeve” for example. As discussed on page 10 of the present application, expressing body fluid with the stimulator sleeve allows the body fluid to be collected and analyzed at alternate sites, which tend to have low blood supplies.

It should be recognized that Garcia does not explicitly disclose expressing fluid from an incision in the manner as recited in claim 99. However, on page 4 of the Office Action, it was alleged in FIG. 4 of Garcia “that the bottom of the lancing device is pressed against the finger before actuation and this pressure will inherently aid blood expression to some degree.” However, there is no inherent disclosure of expressing fluid in such a manner. For an element to be inherently disclosed, it must “necessarily be present in the thing described in the reference.” In re Robertson, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Indeed, inherency “may not be established by probabilities or possibilities . . . The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” 49 USPQ2d at 1951. “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” Ex parte Levy, 17 USPQ2d 1461, 464 (USPTO Bd. of Pat. App. and Interferences 1990) (emphasis in the original).

It is not a necessary consequence that the system 10 in Garcia expresses fluids because it is conceivable, and in fact likely, that the system in Garcia does not express body fluid. First, Garcia teaches lancing fingertips, which have a high blood supply, so there is no need to express fluid. Second, in the FIG. 4 embodiment cited in the Office Action, body fluid is drawn subcutaneously in the needle 90 by a vacuum created by the diaphragm 49 (like a syringe), so there is again no need to express fluid. Even in the FIG. 9 embodiment of Garcia, there is again

no need to express body fluid because the fluid is being collected from the fingertip, which has a high blood supply. Third, expressing of fluid is not a necessary consequence of the system 10 being pressed against the skin because it is conceivable that the system might only lightly touch the skin after lancing such that no expression of fluid occurs. In one embodiment, Garcia mentions that the system 10 is pressed against the skin in order to fire the needle 90, but it does not mention that the system 10 is pressed against the skin to any significant degree after the incision is formed. It is conceivable that the system 10 only barely contacts the skin after forming the incision such that no subcutaneous pressure is created to express fluid. Moreover, it should be recognized that bleeding can be inhibited if a device is pressed too hard against the skin because the device can constrict bleeding from the incision. Given that it is conceivable that the system 10 in Garcia could barely touch the skin so as to not express fluid or be pressed too hard so as to inhibit fluid expression, it is not a necessary consequence that the system 10 in Garcia expresses body fluid so as to make fluid expression inherent to Garcia. Moreover, Cusack fails to remedy this missing feature because it solely concerns lancing the skin and not fluid expression. For these and other reasons, the Applicants respectfully submit that independent claim 99 along with its dependent claims are allowable over the references of record and request that the rejection of these claims under 35 U.S.C. § 103 be withdrawn.

New Claims

Independent Claim 113

Independent claim 113 has been added in order to further clarify the features described in the present application. In particular, claim 113 recites “placing a lancing device against a region of skin where the supply of body fluid is relatively low as compared to a fingertip.” This feature is for example clearly supported at page 10, lines 20-23. It is believed that claim 113 and its dependent claims are allowable over the references of record. For instance, Garcia fails to disclose or suggest “expressing the body fluid from the incision by pressing the lancing device against the skin after said forming the incision” and “positioning the passage opening of the capillary passage into contact with the body fluid on the surface of the skin while the lancing device remains in contact with the skin after said expressing” as is recited in claim 113. As mentioned before, Garcia does not disclose lancing regions other than fingertips. Garcia also fails to disclose expressing fluid from an incision. In addition, as discussed at the bottom of page

4 of the present application, the system 300 in FIG. 9 of Garcia requires precise positioning so as to avoid gapping, which could potentially inhibit fluid collection. Positioning the capillary passage in the manner recited in claim 113 ensures that such gapping is avoided. For these and other reasons, independent claim 113 and its dependent claims are allowable over the references of record.

Independent Claim 117

It is also submitted that new independent claim 117 is allowable over the references of record. For instance, none of the cited references disclose “forming an incision in the skin, wherein said forming the incision includes firing the first disposable towards the skin, wherein during said firing the lancet, the test strip and the capillary passage of the first disposable move together as a single unit towards the skin” and “positioning the passage opening of the capillary passage into contact with body fluid from the incision on the surface of the skin, wherein during said positioning the passage opening of the capillary passage extends past the lancet” (emphasis added). It should be recognized that Garcia fails to disclose a disposable in which the lancet, test strip and capillary passage move together during lancing. Looking at FIG. 9 of Garcia, the lance 300 moves while the rest of the disposable unit 340 (with capillary duct 342) remains stationary. Moreover, the capillary duct 342 is not positioned to collect fluid. Again, as noted on page 4 of the present application, the system 300 in Garcia is unable to compensate for gapping, which can lead to unsuccessful fluid collection. The other cited references disclose devices similar to Garcia in which only the lancet moves during firing (and not the entire disposable). For these and other reasons, independent claim 117 and its dependent claims are allowable over the references of record.

Independent Claim 122

New independent claim 122 recites the features of the electrochemical system described for example on page 12 of the present application. It should be appreciated that when an integrated disposable with a lancet and an electrochemical test strip are fired as a single unit at the skin, making an electrical connection between the meter and test strip can be problematic. As illustrated in FIG. 5 of the present application, the electrical leads (54) of the meter (50) make electrical contact with the test strip (52) when the pusher (24') pushes down the capillary tube

(18) after cutting the incision. It should be recognized that none of the references disclose such a feature. For instance, both Garcia and Smith (U.S. Patent No. 5,108,889) fail to disclose or suggest “forming an incision in the skin with the lancet of the disposable by firing the disposable towards the skin, wherein during said firing the lancet and the test strip of the disposable move together as a single unit towards the skin” and “contacting the electrical leads of the electrochemical meter to the printed electrical circuit paths of the test strip of the disposable after said forming the incision” as is recited in claim 122. Garcia mainly concerns optical analysis systems, which do not require any contacts. In contrast to the recited features, the electrodes 376, 378 (FIG. 10) in Smith are contacted as soon as the chain of sensors 350 are loaded into the meter. Except for the lancets 384, the rest of the sensors 350 remain stationary during lancing such that there is no need to reestablish contact with the electrodes 376, 378 in the sensors 350 after lancing. For these and other reasons, it is believed that independent claim 122 and its dependent claims are allowable over the references of record.

Conclusion

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the Office Action in the most expedient fashion.

In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and an early notice of allowance is earnestly solicited. If after reviewing this amendment the Examiner feels that any issues remain which must be resolved before the application can be passed to issue, the Examiner is invited to contact the undersigned representative by telephone to resolve such issues.

Respectfully submitted,

By /Charles P. Schmal #45,082/

Charles P. Schmal, Reg. No. 45082
Woodard, Emhardt, Moriarty, McNett & Henry LLP
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
(317) 634-3456